DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of Applicants arguments filed on 05/01/2008.

2. Claims 1-20 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 05/01/2008 regarding the rejection of claims 1-20 made by the Examiner under 35 USC 103(a) over Bock et al. (EP 0945134) in view of Struengmann et al (US 6284269) and Parikh (Handbook of Pharmaceutical Granulation Technology, 1997) have been fully considered but they are respectfully not found persuasive.

4. Applicants arguments filed 05/01/2008 regarding the rejection of claims 1-20 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 11/08/2007.

5. In regards to the 103(a) rejection, Applicant asserts the following:

A) The teaching of Struengmann ('269) teaches as essential the inclusion of cyclodextrin as essential to obtaining the greatest solubility in water and therefore '269 teaches away from present invention which does not include cyclodextrin.

6. In response to assertion A, the fact that '269 incorporates cyclodextrin into their meloxicam composition does not result in the teaching away from the instantly claimed invention. MPEP 2111.03 is applied which states that the transitional term 'comprising' is inclusive and does not exclude additional, unrecited elements. Because the instant claims currently use open claim language, cyclodextrin being present in the reference of '269 does not

teach away from the instant invention. It follows that one of ordinary skill would have a reasonable expectation for success in combing the teachings of Bock, '269 and Parikh with a reasonable expectation for success in arriving at the instantly claimed invention.

Maintained Rejections
Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bock et al (EP 0945134; IDS reference) in view of Struengmann et al. (US 6284269) and Parikh (Handbook of Pharmaceutical Granulation Technology, first edition, 1997, issued September 2001, Marcel Dekker, 60-72).**

9. The instantly claimed invention are drawn to water soluble meloxicam granules comprising meglumine salt of meloxicam which contains a binder such as hydroxypropylmethylcellulose (HPMC), a sugar such as aspartame, a flavoring agent such as vanilla and a carrier such as lactose. The proportion of meloxicam is between 0.05% and 4%. The molar ratio of meglumine to meloxicam is 10:8. Further, the water soluble meglumine salt ofmeloxicam granules can contain HPMC, polyvinylpyrrolidone and glucose monohydrate.

10. The teachings of Bock et al. (' 134) appear to be drawn to a formulation (granules and tablets) of meloxicam that are present as sodium and/or meglumine salts (see claim 2). The molar

ratio between meglumine and meloxicam is taught to range from 1.2:1 to 1:1.2 which encompasses the molar ratio of 10:9. The concentration of meloxicam is using tables found on page 11 (examples 5 and 6) shows different meloxicam formulations wherein meloxicam is added in amount of 7.5 mg in a total formulation of 450 mg which corresponds to about a 1.6 wt.% proportion. It is also taught that lactose is a suitable carrier material (see examples 5 and 6, page 11).

11. Although the carriers, binders and flavoring agents instantly claimed are known in the art and their use in such a composition would readily be envisioned by one in the art, ' 134 fails to teach such. Specifically, ' 134 fails to teach the meloxicam granules containing a binder such as HPMC, a sugar such aspartame and a flavoring such as apple. '134 also fails to teach a granule comprising a meglumine melxociam salt, HPMC, polyvinylpyrrolidone, and glucose monohydrate.

12. The teaching of Parikh ('Parikh) teaches a variety of binders and solvents used in the granulation process. It is stated that binders are adhesives which provide the cohesiveness essential for the bonding of the solid particles (i.e. granules) under compression to form a tablet (see pages 60-61). It is clear that the binder excipient is necessary to the formation of tablets. Hence, tablets are nothing more than compressed granules. Binders taught by Parikh include natural and synthetic polymers and sugars. Natural binders include starch and gelatin (see pages 60-63). Synthetic binders include polyvinylpyrrolidone, methylcellulose, and HPMC (see pages 63-66). Sugars can also be used to enhance the bonding properties of the granule formulations. Some sugars include glucose (dextrose), sucrose, and sorbitol (see page 66-67).

13. The teaching of Struengmann et al. ('269) is drawn to a pharmaceutical composition of meloxicam with improved solubility and bioavailability. The meloxicam formulations taught by '269 include among other ingredients lactose, polyvinylpyrrolidone, aspartame and flavoring substances (see column 11, Examples V/8 and V/9). Although these ingredients are used in effervescent tablets, their use would be obvious in water-soluble meloxicam granules because it would be desirable to have sweetness and flavor to improve the palatability.

14. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of '134 with that of Parikh and '269 because in doing so would result in a pharmaceutical dosage form having the anti-inflammatory properties of meloxicam while being palatable to the patient. Although '269 does not specifically teach the meloxicam formulation as that of a granule, it would have been obvious to one of skill in that art that the effervescent tablet is nothing more than compressed granules (see Parkh). And so the tablet of '269 inherently contains granules obviating the inclusion of binders, sweeteners and flavoring agents in the instant claims invention. As the teachings of the references are within the same general field of endeavor (pharmaceuticals), it would have been obvious to one in the art to combine them and arrive at a conventional dosage form with the properties of the instantly claimed invention. Therefore, it would be obvious to one skilled in the art to combine the teaching of '134 with Parkh and '269 with more than a reasonable expectation for success.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
June 3, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615